

## REMARKS

This Response is timely filed within three months of the mailing date of the latest Office Action. Accordingly, no fee is required. 37 CFR § 1.134-1.136.

Claims 1-19, and 21-32 are pending in this application, and Claim 28 is withdrawn. Claims 1, 6, 29, and 30 are amended. No new matter has been added. Reconsideration of the claim rejections in view of the following remarks is respectfully requested.

### **I. The Claims Are Not Anticipated by Preissman or Chin**

The Office rejected Claims 1-5, 10-12, 15-16, 21-25, and 29-32 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,383,190 to Preissman (hereinafter "Preissman"). The Office also rejects Claims 21 and 26 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,156,606 to Chin (hereinafter "Chin"). Applicant respectfully traverses these rejections.

As amended, Claim 1 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising: a shaft having a first end, a middle section, and a second end, wherein the middle section is threaded; and a handle attached to the first end of the shaft; a dispenser hub assembly around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar; and a hollow tube filled with the bone cement for use during the surgical procedure having a first end and a second end, said first end of said hollow tube adapted to be removably attached to the dispenser hub assembly, wherein the shaft is axially displaceable through the

hollow tube for controlled displacement of the bone cement through the second end of the hollow tube. Claims 2-5 and 10-16 depend from Claim 1 and include at least all of the limitations set forth therein.

Claim 21 recites a multi-use cement dispenser kit, comprising: cement delivery means for delivering bone cement into a patient during a surgical procedure, the cement delivery means comprising: a plunger assembly, having a shaft and a handle attached to one end of the shaft; and a dispenser hub assembly, around the shaft of the plunger assembly; and at least one tube pre-filled with bone cement for use during the surgical procedure, the tube adapted to be removably attached to the dispenser hub assembly, wherein the shaft of the cement delivery means is axially displaceable through the tube for controlled displacement of the bone cement through the tube. Claims 22-27 depend from Claim 21 and include at least all of the limitations set forth therein.

As amended, Claim 29 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising a shaft having a first end, a middle section, and a second end; and a handle attached to the first end of the shaft; a dispenser hub assembly disposed around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar; and a hollow tube filled with the bone cement for use during the surgical procedure having a first end and a second end, the first end of the hollow tube adapted to be removably attached to the dispenser hub assembly, wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube.

Claim 30 recites a system for percutaneous delivery of bone cement during a surgical procedure, comprising: a plunger assembly, comprising: a shaft having a first end, a middle section, and a second end, wherein the middle section is threaded; and a handle attached to the first end of the shaft; a dispenser hub assembly around the shaft, the dispenser hub assembly having a collar and a hand-grip attached to the collar, and a threaded portion formed on an interior surface of the collar; and a hollow tube for containing bone cement during the surgical procedure having a first end and a second end, the first end of the hollow tube adapted to be removably attached to the threaded portion of the dispenser hub assembly, wherein the hollow tube includes a funnel-shaped opening at the first end for facilitating the receipt of the bone cement in the hollow tube, and wherein the shaft is axially displaceable through the hollow tube for controlled displacement of the bone cement through the second end of the hollow tube.

Preissman does not disclose the claimed subject matter of the present application. Although Preissman discloses a pressure applicator for delivering an implant material, Preissman fails to teach every feature of the claimed invention. With respect to Claims 1, 21, 29 and 30, Preissman does not disclose a hollow tube adapted to be removably attached to the dispenser hub assembly. The Examiner cites hollow tube 152 as being removably engaged with the dispenser hub. The only figure in Preissman that shows a hollow tube that is applicable to the present invention is Figure 13. Figure 14 does not show a shaft having a threaded middle section, and Figure 18 does not show any type of hollow tube 152. The hollow tube 152 is described in the specification as being "received in the portion 94c and abut against a tapered portion of

the column 94e.” Col. 13, ll. 24-25. The hollow tube 152 rests entirely inside column 94e and is therefore not attached to any portion of column 94e. The hollow tube 152 cannot be removed unless column 96 is removed entirely from the apparatus because the pressure from column 96 is necessary to hold hollow tube 152 in place. An advantage of having the hollow tube being removably attached to the dispenser hub is that the hollow tube can be directly removed without having to first unthread the shaft.

With respect to Claim 10, Preissman requires that the shaft is completely removed to replace the hollow tube 152. Therefore, Preissman cannot disclose the apparatus where the shaft cannot be completely removed because the hollow tube 152 could not be replaced.

With respect to Claim 30, Preissman does not disclose the hollow tube being removably attached to a threaded portion of the dispenser hub. Preissman does not show the hollow tube attached to any portion of the dispenser hub, especially a threaded portion of the dispenser hub.

The Office rejected Claims 21 and 26 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,156,606 to Chin. Applicant respectfully traverses these rejections.

Chin does not disclose a tube adapted to be removably attached to the dispenser hub assembly. The cement cartridge 12 is described in the specification as secured to the injection gun 10. See Chin Col. 3, ll. 34-35. The specification in Chin is silent on whether or not the cement cartridge 12 is removable. The issue is not addressed in the specification, but more importantly, the specification does not suggest or teach a need

for the cartridge to be removable. The only language used regarding the cartridge is that it is secured to the injection gun. Even if the cement cartridge 12 is removable, the design has the exact same problem that is described above in Preissman. The cement cartridge 12 could only be inserted when the plunger (not numbered) is removed. The cement cartridge 12 is not attached to the injection gun 10. The cement cartridge 12 is only secured by the pressure of the shaft and can only be removed when the shaft is removed.

For at least these reasons, Applicant respectfully submits that Preissman and Chin fail to disclose Applicant's claimed invention. Accordingly, Applicant requests reconsideration and withdrawal of the rejections.

## **II. The Claims are Non-Obvious**

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Preissman in view of U.S. Patent No. 6,352,585 to Diesso (hereinafter "Diesso"). Claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Preissman in view of U.S. Patent No. 5,603,701 to Fischer (hereinafter "Fischer"). Claims 21-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,395,007 to Bhatnagar et al. (hereinafter "Bhatnagar") in view of Preissman. Claim 22 is rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,156,606 to Chin. Applicant respectfully traverses these rejections.

In order to establish a *prima facie* showing of obviousness under Section 103, the Examiner must set forth three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally

available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. See MPEP §§ 706.02(j), 2142 (8th ed., 2nd Rev., 2004). Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference (or the references when combined must teach or suggest all of the claim limitations. *Id.*

The only apparent motivation for combining the references above arises from Applicant's disclosure and the claimed invention itself, which constitutes impermissible hindsight motivation and cannot be relied upon as a reason to combine references. See, e.g., *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

With respect to Claim 21, taken alone or in combination, neither Bhatnagar nor Preissman teach or suggest the claimed subject matter. Although Preissman discloses a pressure applicator for delivering an implant material, Preissman fails to teach every feature of the claimed invention as disclosed above. Preissman does not disclose a hollow tube adapted to be removably attached to the dispenser hub assembly, as presently claimed. Moreover, Preissman is silent as to the use of a multi-use kit for delivery of bone cement. Although Bhatnagar teaches the use of a kit including an injection device, Bhatnagar also fails to teach the elements of the claimed invention, including a hollow tube pre-filled with bone cement removably attached to the dispenser hub assembly. The Examiner states that Bhatnagar discloses "a tubing assembly removably attached to the cement delivery means". This assertion is insufficient to render the claimed subject matter obvious. Bhatnagar fails to teach either a dispenser hub assembly or a hollow tube pre-filled with bone cement adapted to be removably

attached to the dispenser hub assembly, as presently claimed. It is well established that a prior art reference or combination of references must teach or suggest all of the claim limitations. Accordingly, Preissman and Bhatnagar fail to establish a *prima facie* showing of obviousness because neither reference teaches a hollow tube pre-filled with bone cement removably attached to the dispenser hub assembly. The tubing described in Bhatnagar is neither pre-filled with bone cement nor attached to the dispenser hub assembly. The examiner suggests that the elements in Bhatnagar are functional equivalents of the elements in Preissman. However, the tubing assembly 44 is not a function equivalent of the hollow tube 152 in Preissman and would not work if it was substituted. These two elements are performing different functions. Therefore, the combination of these two references fails to teach the claimed subject matter because neither reference teaches the claimed element.

In view of the foregoing, Applicant submits that the cited references do not teach or suggest the claimed subject matter and respectfully requests withdrawal of the rejections of the Claims under Section 103.

### **III. Conclusion**

Applicant respectfully submits that the Claims of the present invention define patentable subject matter and that the application is in condition for allowance. Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the below listed telephone number.

It is believed that no fee is required for the present amendment. In the event that a fee is required, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicant's undersigned representative to arrange payment.

Respectfully submitted,



Dated: December 8, 2005

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JOHN N. COULBY, Reg. No. 43,565  
MICHAEL S. KERNS, Reg. No. 51,233  
COLLIER SHANNON SCOTT, PLLC  
3050 K Street, N.W., Suite 400  
Washington, D.C. 20007  
(202) 342-8400